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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,501	04/12/2001	David J. Ballance	6832.0012-00	2463
22852	7590	12/16/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/832,501

**Applicant(s)**

BALLANCE ET AL.

**Examiner**

Hope A. Robinson

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 and 61-68 is/are pending in the application.
- 4a) Of the above claim(s) 22-29 and 61-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10, 13, 14 and 17-21 is/are rejected.
- 7) ☒ Claim(s) 4, 11-12 and 15-16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/11/02 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. Applicant's response to the Office Action mailed June 22, 2004 on September 21, 2004, is acknowledged.
2. Claims 30-60 have been canceled. Claims 61-68 have been added. Claims 1-2, 7-8, 23-26 and 29 have been amended. Claims 1-29 and 61-68 are pending. Claims 1-21 are under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The following grounds of objection/rejection are or remain applicable:

***Drawing***

5. The Drawings filed on March 11, 2002 are objected to because Figures 6, 7 and 15A-D are extremely pale in color.

Correction is required

***Specification***

6. The specification is objected to because of the following informalities:
  - (a) The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The

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use of the trademarks such as SULFAMETHOXAZOLE<sup>TM</sup>, DAPSONE<sup>TM</sup>, PENTAMIDINE<sup>TM</sup> for example, have been noted in this application (see page 97). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

(b) The specification is objected to because on page 58, lines 13-14, blank spaces appear in reference to the ATCC deposit number.

Correction is required.

***Claim Rejections - 35 U.S.C. § 103***

7. Claims 1-3, 5-10, 13-14 and 17-21 remain rejected under 35 U.S.C. 103(a) for the reasons of record.

***Response to Applicant's Arguments:***

Applicant's response filed on September 21, 2004 has been considered. The response on page 14 state that a *prima facie* case of obviousness must have some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. It is further stated that the combination of the references must provide some reasonable expectation of success for the claimed invention. On pages 15+ of the response it is stated that the primary reference focuses on

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an albumin fused to a growth hormone and only mentions other proteins in the background section of the reference. This argument is not persuasive.

The primary reference (DELTA BIOTECHNOLOGY LTD.) provides motivation to combine the references because it is disclosed that albumin is useful as a component of a fusion protein as it is a stabilizer and transporter of other proteins. The reference does not place any limitation on the types of proteins and provides examples such as polypeptide, antibody, peptide, fragments or variants thereof. Further, the primary reference indicates that the half-life of the fusion protein is greater than the half-life of the fusion partner by itself, another benefit of using albumin. Thus, the primary reference clearly establishes that albumin is a good fusion partner because it adds stability, enhances the half-life of the other protein in the fusion and is a transporter. Interferon alpha is known in the prior art as a therapeutic protein and fusion with this protein is also known in the prior art. Further the secondary reference (CETUS CORPORATION) discloses the stabilization of interferon alpha as a result of the albumin, which establishes that albumin has the ability to provide stability to interferon alpha that interferon alpha by itself would not have, and the albumin would have to interact with the interferon alpha to provide such stability. Therefore, one of skill in the art would be motivated to fuse interferon alpha with albumin with a reasonable expectation of success because the primary reference teaches the advantages of fusions with albumin and sets no limitations on the type of protein and the secondary reference teaches albumin in association with the subject protein for stability purposes and the subject protein is known to be fusable. Thus, the claimed invention is *prima facie* obvious. Thus, the rejection remains.

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*Conclusion*

8. No claims are presently allowable.

9. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957.

The examiner can normally be reached on Monday-Friday.

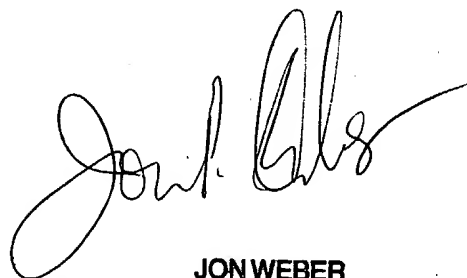
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MSC *HR*

Patent Examiner *12/7/04*

A handwritten signature in black ink, appearing to read "Jon Weber", with a large, stylized loop at the end.

**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**